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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,719	06/23/2003	Tine Holland Frimann	433.015	8753

20311 7590 07/02/2004

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,719	FRIMANN, TINE HOLLAND	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Applicant's April 27, 2004 response is acknowledged. The traversal is on the ground(s) that the vaccine formulation of Group I is related with the base stock solution, the diluent, of Group II. Applicant submits that the base stock solution is used in the vaccine formulation. This is found persuasive. Therefore, claims 9-11 are rejoined with Group I.

Status of Claims

2. Claims 1-11 are currently pending and under examination. For clarification purpose, the total number of claims that is present in the instant case is 11 claims, not 12 as previously noted by the Examiner in the Restriction requirement and Applicant's April 27, 2004 response.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Currently as written, it is unclear what is intended by "paraben esters". Parabens are esters of p-hydroxybenzoic acid. Therefore, parabens all ready contain an ester group. Thus, currently, as written, it is unclear what is intended by the recitation "paraben esters".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by NG et al., WO 98/34594, published 08/13/1998.

The claims are directed to a vaccine formulation and a base stock solution comprising an immunogen, a preservative, and suitable pharmaceutically acceptable excipients for vaccines, wherein the preservative is a combination of at least two paraben and 2-phenoxyethanol. The claims further limit the parabens to methyl, ethyl, propyl, and butyl p-hydroxybenzoate. The claims further limit the preservative to be a combination of methyl p-hydroxybenzoate, propyl p-hydroxybenzoate and 2-phenoxyethanol. The claims further require that the vaccine excipients selected from a group consisting of diluents, stabilizers, adjuvants, preservatives, buffers, surfactants, viscosity controlling agents and osmotic pressure controlling agents. Additionally, the claims require that the formulation comprise aluminum hydroxide gel as an adjuvant.

NG et al. teaches a vaccine formulation and a base stock solution that comprises an immunogen, pharmaceutically acceptable excipients, aluminum hydroxide, a preservative; wherein the preservative is a combination of two paraben esters, methyl and ethyl, and 2-phenoxyethanol; see abstract of Ng et al. reference. The pharmaceutically acceptable excipient that is included in the vaccine formulation taught

by Ng et al. includes a buffer. Therefore, NG et al. anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al., WO 91/01143, published 02/07/1991.

The claims are directed to a vaccine formulation and a base stock solution comprising an immunogen, a preservative, and suitable pharmaceutically acceptable excipients for vaccines, wherein the preservative is a combination of at least two paraben and 2-phenoxyethanol. The claims further limit the parabens to methyl, ethyl, propyl, and butyl p-hydroxybenzoate. The claims further limit the preservative to be a combination of methyl p-hydroxybenzoate, propyl p-hydroxybenzoate and 2-phenoxyethanol. The claims further require that the vaccine excipients selected from a group consisting of diluents, stabilizers, adjuvants, preservatives, buffers, surfactants, viscosity controlling agents and osmotic pressure controlling agents. Additionally, the claims require that the formulation comprise aluminum hydroxide gel as an adjuvant. The claims also require that that the different components of the formulation be at a various concentrations.

Pillai et al. teaches a vaccine formulation and a base stock solution that comprises an adjuvant, immunogen, aluminum hydroxide, and a preservative, see abstract. The preservative disclosed by Pillai et al. includes methyl paraben, ethyl paraben, and 2-phenoxyethanol; wherein methyl and ethyl parabens are also known as methyl, ethyl p-hydroxybenzoate, see lines 21-24 of page 3.

Pillai et al. does not teach that the preservative be a combination of at least two parabens and 2-phenoxyethanol.

However, as mentioned above, Pillai et al. does teach methyl paraben, ethyl paraben, and 2-phenoxyethanol are preservatives.

MPEP § 2144.06 recites the conclusions of *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA), "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art." Therefore, since the instantly claimed invention is drawn to combining old ingredients, each known to be preservatives in a vaccine formulation, the combination of their additive effects renders the invention prima facie obvious and does not exhibit an unexpected result. Therefore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the claimed invention, absent of unexpected results to the contrary.

Additionally, Pillai et al. does not teach the specific concentrations that are recited in the instant claims. However, MPEP § 2144.05 states that "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, the instantly claimed concentrations are not inventive because it would have been obvious for one of ordinary skill in the art to experiment with different concentrations as part of routine experimentation. One of ordinary skill in the art would have been motivated to experiment with the different concentrations of the preservative(s) to enhance the preservation of a vaccine. One of ordinary skill in the art would have had a reasonable expectation of success for producing the claimed invention because such experimentation is part of routine experimentation, absent unexpected results to the contrary.

9. Claims 6 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. in view of Marciani, U.S. Patent No. 6080725, published 06/27/2000.

The claims further require that the vaccine formulation comprise Quillaja saponin.

The relevance of Pillai et al. is discussed above. Pillai et al. does not teach the use of saponin. However, Marciani teaches that saponin, Quillaja saponin, have an antimicrobial activity. Marciani also teaches the use of saponin in vaccine formulation.

One of ordinary skill in the art at the time of the claimed invention was made would have been motivated to combine the teachings of Marciani and Pillai et al. because Pillai et al. teaches a vaccine formulation and Marciani teaches a vaccine formulation that contains saponin, wherein Marciani et al. teaches that saponin have an antimicrobial activity. One of ordinary skill in the art at the time the invention was made

would have had a reasonable expectation of success for combining saponin with the vaccine formulation of Pillai et al. because Pillai et al. teaches a vaccine formulation and Marciani teaches a vaccine formulation too. Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

10. Claims 6 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al. in view of Marciani, U.S. Patent No. 6080725, published 06/27/2000.

The relevance of Ng et al. is discussed above. Ng et al. does not teach the use of saponin. However, Marciani teaches that saponin, Quillaja saponin, have an antimicrobial activity. Marciani also teaches the use of saponin in vaccine formulation.

One of ordinary skill in the art at the time of the claimed invention was made would have been motivated to combine the teachings of Marciani and Ng et al. because Ng et al. teaches a vaccine formulation and Marciani teaches a vaccine formulation that contains saponin, wherein Marciani et al. teaches that saponin have an antimicrobial activity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining saponin with the vaccine formulation of Ng et al. because Ng et al. teaches a vaccine formulation and Marciani teaches a vaccine formulation too. Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

11. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al.

The claims also require that that the different components of the formulation be at a various concentrations.

The relevance of Ng et al. is discussed above.

Ng et al. does not teach the specific concentrations that are recited in the instant claims. However, MPEP § 2144.05 states that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, the instantly claimed concentrations are not inventive because it would have been obvious for one of ordinary skill in the art to experiment with different concentrations as part of routine experimentation. One of ordinary skill in the art would have been motivated to experiment with the different concentrations of the preservative(s) to enhance the preservation of a vaccine. One of ordinary skill in the art would have had a reasonable expectation of success for producing the claimed invention because such experimentation is part of routine experimentation, absent unexpected results to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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